

REMARKS

The Office Action mailed January 23, 2007, has been received and reviewed. By the present Response and Amendment, Claims 2, 3, and 18 are canceled and Claims 1, 4, 6, 9, 11, 17, and 19 are amended, and new Claim 21 is added. No new matter is introduced.

Claim Rejections Under 35 USC § 112

Claims 3, 4, 9-16 and 19 have been objected to due to minor informalities. Correction has been made.

Claim Rejections Under 35 USC § 102

Claims 1-5, 7, 9, 10, 12, 13 and 16-20 stand rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by U.S. Patent No. 5,569,287 to Tezuka et al. Claims 2 and 3 are canceled. The applicant respectfully traverses the rejection of the other claims.

Claims 1 and 17 are amended to clarify that the drive member is stopped from moving forward before the lancet reaches the extended position, but the lancet is not, and so the lancet decouples from the drive member and continues moving forward under its own momentum until it reaches the extended position, as shown in Figs. 3 and 4. In this way, the mass of the drive member is not behind and bearing on the lancet when the lancet begins puncturing the skin. The lancet by itself, decoupled from the drive member, has a lower mass and momentum. A reduction in the mass and momentum of the lancet and components bearing on it (e.g., drive member, drive spring, lancet holder) reduces oscillations and vibrations of the lancet, and has been found to reduce the sensation of pain perceived by the subject whose skin is being lanced.

On the other hand, the Tezuka device has a sliding means 130 that pushes down a needle 205 as the needle punctures the skin. As shown in Fig. 3, the sliding means 130 and the cylinder 110 housing it have cooperating shoulders for stopping the forward travel of the sliding means *after the needle 205 has begun puncturing the skin*. So when the

needle 205 is puncturing the skin, the mass of the sliding means 130 is behind and bearing on it. This is the conventional way that lancing devices work and part of what the present invention improves on.

In addition, there is no teaching in the Tezuka reference to decouple the needle 205 from the sliding means 130 during skin puncturing to reduce pain. The needle 205 and the sliding means 130 of the Tezuka device do in fact decouple, but not during skin puncturing and only so that the puncturing tip 200 (with the needle 205) can be replaced on the main body 100 (with the sliding means 130). The teachings of the Tezuka reference do not relate to reducing pain but rather to obtaining a predetermined amount of blood in a blood conduit for subsequent analysis.

For these reasons, the applicant respectfully submits that amended Claims 1 and 17 are in condition for allowance. Claims 4, 5, 7, 19, and 20, and new Claim 21, are dependent from Claims 1 and 17, so these dependent claims are also believed to be in condition for allowance.

Claim 9 is not substantively amended because as written it defines the drive member being stopped and decoupled from the lancet before the lancet reaches the extended position, with the lancet continuing on to the extended position by itself, as shown in Figs. 3 and 4. As discussed above, this is not disclosed in the Tezuka reference. Accordingly, the applicant respectfully submits that Claim 9 is in condition for allowance. Claims 10, 12, 13, and 16, are dependent from Claim 9, so these dependent claims are also believed to be in condition for allowance.

In addition, Claims 12 and 13 define the lancing device including a trigger mechanism with a latch for holding in place and releasing the drive member, and a cocking mechanism for retracting the drive member. On the other hand, the Tezuka device does not have a trigger or cocking mechanism at all. Instead, the device has a piston 120 that is manually pushed down by a user's finger (see Fig. 5) to active the device, without retracting the needle or another component to charge a drive mechanism. For this

additional reason, the applicant respectfully submits that Claims 12 and 13 are in condition for allowance.

New Claim 21 is added to define that, after the lancet is driven to the extended position to puncture the skin, a return spring returns the lancet toward the retracted position, into engagement with the drive member, and into a neutral rest position. As discussed above, in the Tezuka device the sliding means 130 is in pushing contact with the needle 205 all the way to the extended position. The needle 205 cannot *return* to engagement with the sliding means 130 if they are still engaged. For this additional reason, the applicant respectfully submits that new Claim 21 is in condition for allowance.

Claim Rejections Under 35 USC § 103

Claims 6 and 11 stand rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over U.S. Patent No. 5,569,287 to Tezuka et al. in view of U.S. Patent No. 5,368,047 to Suzuki et al. Claims 8, 14 and 15 stand rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over U.S. Patent No. 5,569,287 to Tezuka et al. in view of U.S. Patent No. 5,558,402 to Chelak et al. The claims are dependent from Claims 1 and 9, which are now allowable, so these dependent claims are also believed to be in condition for allowance.

In addition, Claims 6 and 11 as amended better define the arrangement of the drive spring being received within an opening in the rear/distal end of the drive member. When the cocking arm/rod is retracted or otherwise operably moved, the drive member is retracted and the drive spring is compressed within the drive member opening. Then when the lancing device is activated the drive spring discharges within the drive member opening to launch the drive member toward the lancet. In this way, a proximal/forward end of the drive spring is closer to the lancet than the distal/rear end of the drive member, so that the drive spring does not push the drive member from the drive member distal end. Because the drive member is not pushed from behind, it tends to travel in a more precisely straight

line, which reduces oscillations and vibrations, thereby reducing the perceive pain of the lancing.

On the other hand, the Suzuki device has a lancet that is pushed substantially from behind by a drive spring. This is the conventional way that lancing devices work and part of what the present invention improves on. The Suzuki device does not disclose, suggest or teach sinking the drive spring substantially within a rear opening in the drive member to improve guidance and reduce oscillations and vibrations, as is claimed. For this additional reason, the applicant respectfully submits that Claims 6 and 11 are in condition for allowance.

CONCLUSION

In view of the amendments submitted herein and the above comments, it is believed that all grounds of rejection are overcome and that the application has now been placed in full condition for allowance. Accordingly, Applicant earnestly solicits early and favorable action. Should there be any further questions or reservations, the Examiner is urged to telephone Applicant's undersigned attorney at (770) 984-2300.

Respectfully submitted,

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